

# Drugs@FDA: FDA Approved Drug Products

**f** **SHARE** ([HTTPS://WWW.FACEBOOK.COM/SHARER/SHARER.PHP?U=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDE  
R/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS&APPLNO=021217](https://www.facebook.com/sharer/sharer.php?u=https://www.accessdata.fda.gov/scripts/cder/daif/index.cfm?event=overview.process&applno=021217))

**🐦** **TWEET** ([HTTPS://TWITTER.COM/INTENT/TWEET/?TEXT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&URL=HTTPS://  
WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS&APPLNO=021217](https://twitter.com/intent/tweet?text=Drugs@FDA: FDA Approved Drug Products&url=https://www.accessdata.fda.gov/scripts/cder/daif/index.cfm?event=overview.process&applno=021217))



**✉** **EMAIL** ([MAILTO:?SUBJECT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&BODY=HTTPS://WWW.ACCESSDATA.FD  
A.GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS&APPLNO=021217](mailto:?subject=Drugs@FDA: FDA Approved Drug Products&body=https://www.accessdata.fda.gov/scripts/cder/daif/index.cfm?event=overview.process&applno=021217))

[Home \(index.cfm\)](#) | [Previous Page](#)

New Drug Application (NDA): 021217

Company: SPECGX LLC

**✉** **EMAIL** ([MAILTO:?SUBJECT=DRUGS@FDA: FDA APPROVED DRUG PRODUCTS&BODY=HTTP://WWW.ACCESSDATA.FDA.  
GOV/SCRIPTS/CDER/DAF/INDEX.CFM?EVENT=OVERVIEW.PROCESS%26VARAPPLNO=021217](mailto:?subject=Drugs@FDA: FDA Approved Drug Products&body=http://www.accessdata.fda.gov/scripts/cder/daif/index.cfm?event=overview.process%26varapplno=021217))

- [Medication Guide \(https://www.accessdata.fda.gov/drugsatfda\\_docs/la-  
bel/2018/021217s023s024lbl.pdf#page=30\)](https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/021217s023s024lbl.pdf#page=30)
- [REMS \(http://www.accessdata.fda.gov/scripts/cder/remis/index.cfm?  
event=RemisDetails.page&REMS=17\)](http://www.accessdata.fda.gov/scripts/cder/remis/index.cfm?event=RemisDetails.page&REMS=17)
- [Summary Review \(http://www.accessdata.fda.gov/drugsat-  
fda\\_docs/nda/2010/021217s000SumR.pdf\)](http://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/021217s000SumR.pdf)

## Products on NDA 021217

[CSV](#)[Excel](#)[Print](#)

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	R
EXALGO	HYDROMORPHONE HYDROCHLORIDE	8MG	TABLET, EXTENDED RELEASE; ORAL	Discontinued	None	Yes

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	R
EXALGO	HYDROMORPHONE HYDROCHLORIDE	12MG	TABLET, EXTENDED RELEASE;ORAL	Discontinued	None	Yes
EXALGO	HYDROMORPHONE HYDROCHLORIDE	16MG	TABLET, EXTENDED RELEASE;ORAL	Discontinued	None	Yes
EXALGO	HYDROMORPHONE HYDROCHLORIDE	32MG	TABLET, EXTENDED RELEASE;ORAL	Discontinued	None	Yes

Showing 1 to 4 of 4 entries

**Approval Date(s) and History, Letters, Labels, Reviews for NDA 021217****Original Approvals or Tentative Approvals**

CSV

Excel

Print

Action Date	Submission	Action Type	Submission Classification	Review Priority; Orphan Status	Letters, Review
03/01/2010	ORIG-1	Approval	Type 3 - New Dosage Form	STANDARD	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/nda/021217Orig1s01.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/nda/021217Orig1s01.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/nda/021217Orig1s01.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/nda/021217Orig1s01.pdf</a> ) Review ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/nda/021217Orig1s01.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/nda/021217Orig1s01.pdf</a> ) Summary Review

Showing 1 to 1 of 1 entries

**Supplements**

CSV

Excel

Print

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package
-------------	------------	--	---

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package
09/18/2018	SUPPL-24	Labeling- Package Insert	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/018182.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/018182.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/letter/2018/018182.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/letter/2018/018182.pdf</a> )
09/18/2018	SUPPL-23	REMS - MODIFIED - D-N-A	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/018183.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/018183.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/letter/2018/018183.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/letter/2018/018183.pdf</a> )
05/26/2017	SUPPL-21	REMS-Modified	Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/letter/2017/052621.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/letter/2017/052621.pdf</a> )
12/16/2016	SUPPL-19	Labeling- Package Insert	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/121619.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/121619.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/letter/2016/121619.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/letter/2016/121619.pdf</a> )
09/30/2016	SUPPL-20	REMS - MODIFIED - D-N-A	Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/letter/2016/093020.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/letter/2016/093020.pdf</a> )
04/20/2016	SUPPL-17	REMS-Modified	Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/letter/2016/042017.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/letter/2016/042017.pdf</a> )
06/26/2015	SUPPL-15	REMS-Modified	Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/letter/2015/062615.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/letter/2015/062615.pdf</a> )
06/02/2015	SUPPL-9	Labeling- Package Insert	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/060209.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/060209.pdf</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/letter/2015/060209.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/letter/2015/060209.pdf</a> )

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package
08/19/2014	SUPPL-14	REMS-Modified	Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/...">https://www.accessdata.fda.gov/drugsatfda_docs/...</a> )
06/17/2014	SUPPL-12	Labeling-Medication Guide, REMS-Proposal, Labeling-Package Insert	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/...">https://www.accessdata.fda.gov/drugsatfda_docs/...</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/...">https://www.accessdata.fda.gov/drugsatfda_docs/...</a> )
04/16/2014	SUPPL-13	Labeling-Package Insert	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/...">https://www.accessdata.fda.gov/drugsatfda_docs/...</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/...">https://www.accessdata.fda.gov/drugsatfda_docs/...</a> )
04/15/2013	SUPPL-6	REMS-Modified	Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/...">https://www.accessdata.fda.gov/drugsatfda_docs/...</a> )
03/18/2013	SUPPL-5	Labeling-Package Insert	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/...">https://www.accessdata.fda.gov/drugsatfda_docs/...</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/...">https://www.accessdata.fda.gov/drugsatfda_docs/...</a> )
08/24/2012	SUPPL-4	Labeling-Package Insert, REMS-Modified	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/...">https://www.accessdata.fda.gov/drugsatfda_docs/...</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/...">https://www.accessdata.fda.gov/drugsatfda_docs/...</a> )
07/09/2012	SUPPL-2	Labeling, REMS-Modified	Label (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/...">https://www.accessdata.fda.gov/drugsatfda_docs/...</a> ) Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/...">https://www.accessdata.fda.gov/drugsatfda_docs/...</a> )
03/24/2010	SUPPL-1	REMS-Modified	Letter (PDF) ( <a href="https://www.accessdata.fda.gov/drugsatfda_docs/...">https://www.accessdata.fda.gov/drugsatfda_docs/...</a> )

Showing 1 to 16 of 16 entries

**Labels for NDA 021217**

